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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,748	08/04/2000	Barbara A. Gilchrest	0054.1087-010	2365

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EXAMINER	
GUCKER, STEPHEN	
ART UNIT	PAPER NUMBER
1647	12

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/632,748	Gilchrest et al.
Examiner	**Group Art Unit**
Stephen Gucker	1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 8/30/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-32 is/are pending in the application.

Of the above claim(s) 1-9, 12-13, & 16-32 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 10-11 & 14-15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6 & 8

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Serial Number: 09/632,748

Art Unit: 1647

Part III DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.

2. Applicant's election with traverse of Group VII, claims 10-12 and peptide sequence KGA in Paper No. 11 is acknowledged. The traversal is found partially persuasive. New Group II, claims 10-11 and 14-15 and peptide sequence KGA will be examined. Claims 12 and 16 are withdrawn as being drawn to a non-elected sequence.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-9, 12-13, and 16-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 10 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims which recite pseudo-ligands that are defined as any substance which mimics a neurotrophin's ability to bind to the p75 nerve growth factor receptor fail to meet the description requirement of U.S.C. 112, 1st paragraph.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The disclosure has sufficient written description for methods employing substances such as NGF, a biologically active fragment of NGF that binds to p75 NGFR, neurotrophin-3, and neurotrophin-4/5. The skilled artisan can readily envision what all these substances comprise. However, unlike the substances set forth above, the skilled artisan cannot envision the detailed chemical structure of the encompassed pseudo-ligands recited in the instant claims because all such products recited in the instant methods are defined by their functional, not chemical or structural attributes, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of manufacturing or testing the recited products used in the claimed methods. Because of the use of a functional limitation for a product recited in the instant methods, the recited product used in the method claims would encompass substances of any nature (organic chemicals, inorganic chemicals, proteins, polypeptides, peptides, etc.) that have absolutely no chemical or structural similarities with any NGF or neurotrophin known in the art or envisioned by the specification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a

potential method for making or testing it. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. (See page 1115.) Lacking any chemical or structural claim limitation as to what does and does not constitute a pseudo-ligand which is defined as anything which mimics NGF's ability to bind to the p75 nerve growth factor receptor (see specification, pages 14-15), the scope of the terms reads on many products that are not supported or even envisioned by the disclosure, and the specification cannot put the vast majority of putative pseudo-ligands into the hands of the skilled artisan because of the lack of adequate written description of the chemical structure of these substances. This is particularly true in the protein and peptide arts because of the unpredictable nature of structural and functional changes produced by amino acid substitutions, deletions, or additions.

6. Claims 10 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods employing substances such as neurotrophin or a biologically active fragment thereofof, does not reasonably provide enablement for methods using pseudo-ligands. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The term "pseudo-ligand" lacks sufficient written description, guidance, and examples in the specification. "Pseudo-ligand" does not provide any chemical or

structural limitations for the product claimed, but only describes the product by its function, unlimited and unfettered by what is enabled by the disclosure. Lacking any chemical or structural description as to what does and does not constitute an "pseudo-ligand", the scope of the term reads on many products that are not supported or even envisioned by the disclosure, and the specification cannot put the vast majority of "pseudo-ligands" into the hands of the skilled artisan without forcing undue experimentation. This is particularly true in the protein and peptide arts because of the unpredictable nature of structural and functional changes produced by amino acid substitutions, deletions, or additions.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 10-11 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Reams. Reams discloses a method of injecting NGF into the skin of mice, which resulted in a variety of effects on hair growth and pigmentation (Figures 1-7). The process steps of Reams are identical to the process steps of the instant claims, and would inherently produce the results claimed by Applicants (see especially the dark hair growth of Figure 3 and the "dense zone of well-formed, black minute hairs" mentioned on page 553), even if Reams does not explicitly set forth the mechanism of action for his results. By injecting NGF directly into the skin of mice,

NGF contacted p75 NGFR on melanocytes as it spread from the injection site (Reams, page 556-557), thereby meeting all of the limitations of the instant claims.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

November 18, 2002

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600